

# Legislative Analysis



## EPINEPHRINE DEVICES FOR SCHOOLS: POLICIES & PRESCRIPTIONS

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**House Bill 4352 (reported from committee without amendment)**

**House Bill 4353 (Substitute H-2)**

**Sponsor: Rep. Lisa Posthumus Lyons**

**Committee: Education**

### **First Analysis (10-8-13)**

**BRIEF SUMMARY:** The bills would allow physicians to prescribe and pharmacists to dispense auto-injectable epinephrine devices to school boards and limit their liability; require that auto-injectable epinephrine devices be present at all public schools, including charter schools, and limit the liability of certain school employees when they in good faith administered an auto-injectable epinephrine device to an individual consistent with policies described in the bill.

**FISCAL IMPACT:** The bill could create additional, although likely minimal, costs for local school districts and public school academies by requiring staff training and requiring them to possess at least two epinephrine auto-injectors per school building.

### **THE APPARENT PROBLEM:**

According to the Michigan Allergy and Asthma Society, an estimated eight percent of American children—15 million youngsters—suffer from food allergies, about one in every 13 children. In addition, an estimated three percent of the population suffers from stinging insect allergy which can be potentially fatal to a child, as well.

The incidence of allergies in young people is on the rise. That increase is attributed to better detection as medical diagnostic tests improve and to an increasing imbalance in the human immune system.

There are nonlife threatening allergic reactions such as rashes and hives or swelling that can be relieved with antihistamines. However, sometimes when youngsters experience an allergic reaction, they have difficulty breathing, as their airways close. Their allergic reactions, left unattended, can result in death.

All allergic reactions are called anaphylaxis—any sudden and severe allergic reaction that may affect the whole body. Symptoms can include hives; lip, tongue and throat swelling; nausea, vomiting diarrhea, cramping; shortness of breath, wheezing, coughing; drop in blood pressure; and loss of consciousness.

Epinephrine—a form of adrenaline from the adrenal gland—is the only chemical that can reverse the life threatening symptoms of severe allergic reactions, and protect vital organs. The average time to respiratory or cardiac arrest due to food allergy is 30

minutes, according to the Allergy and Asthma Network. The drug epinephrine is available in an auto-injector delivery system, such as Auvi-Qs, and EpiPens. These are prescription devices that contain a premeasured dose of epinephrine. The needles (designed to penetrate clothing) are protected inside the devices until you push the injector against your thigh. According to committee testimony, epinephrine can reverse life-threatening allergic symptoms in as little as five seconds. See ***Background Information***.

Nearly every state has laws protecting students' right to carry and use anaphylaxis medications. Further, 27 states have enacted laws to require or allow schools to stock and administer unassigned anaphylaxis medications. Four additional states are considering such laws. These laws allow school personnel to inject students having allergic reactions with epinephrine--a form of adrenaline having few negative side effects that gives nearly instant relief by unblocking air passages. States are adopting new laws in response to H.R. 2094 which passed the U. S. House of Representatives in July 2013, and was introduced in the U.S. Senate in early September 2013.

Legislation has been introduced in Michigan to require public school officials to have epinephrine injectors on the school site, and to train up to two people to administer the drug to individuals who are in the throes of allergic reactions.

### ***THE CONTENT OF THE BILLS:***

The bills would amend two separate acts to address the use of auto-injectable epinephrine devices in schools.

House Bill 4352 would amend the Public Health Code (MCL 333.17745, 333.17751, 333.17754, and 333.17757) to allow physicians to prescribe and pharmacists to dispense auto-injectable epinephrine devices to school boards and limit their liability.

House Bill 4353 (H-2) would amend the Revised School Code (MCL 380.1178 and 380.1179) to require that auto-injectable epinephrine devices be present at all public schools, including charter schools, and to limit the liability of certain school employees when they in good faith administer an auto-injectable epinephrine device to a student consistent with policies described in the bill.

House Bill 4352 is tie-barred to House Bill 4353 (H-1) so that it could not go into effect unless House Bill 4353 (H-1) also was enacted into law. A more detailed description of each bill follows.

#### ***House Bill 4352***

The bill would amend *the Public Health Code* to specify that a dispensing prescriber or pharmacist may dispense auto-injectable epinephrine to a school board. When issuing such a prescription, the prescriber, dispensing prescriber, or pharmacist must insert the name of the school board as the name of the patient. A school employee who is a

licensed registered professional nurse or who is trained in the administration of an epinephrine auto-injector may possess and administer the epinephrine auto-injector.

Under the bill, a prescriber who issues a prescription for, or a pharmacist who dispenses, auto-injectable epinephrine is not liable in a civil action for personal injury or death proximately caused by the professional negligence or malpractice of the prescriber, dispensing prescriber, or pharmacist. However, this protection from liability does not apply if the negligent conduct or malpractice is gross negligence.

Now under the law, a pharmacist must furnish to the purchaser of a prescription drug a receipt containing the brand name of the drug, the name of the manufacturer or supplier, the strength of the drug, the quantity dispensed, the name and address of the pharmacy, the serial number of the prescription, the date the prescription was originally dispensed, the name of the prescriber, the name of the patient for whom the drug was prescribed, and the price of the drug. House Bill 4352 would retain all of these provisions, but require that the name of the school board be used in lieu of the name of the patient for whom the drug was prescribed.

***House Bill 4353 (Substitute H-2)***

The bill would amend the Revised School Code to require that auto-injectable epinephrine devices be present at all public schools.

Under the bill, a school board would have to ensure that in each school it operates with an instructional and administrative staff of 10 or more people, there were at least two employees at the school trained in the appropriate use and administration of an epinephrine auto-injector. In each school having fewer than 10 instructional and administrative staff, there would have to be at least one employee trained to appropriately administer an epinephrine auto-injector.

Further, the bill requires that a school board develop and implement policies that are consistent with the Michigan Department of Education's "medication administration guidelines" (as revised under subsection 4 of the bill), and that provide for the possession of at least two epinephrine auto-injectors in each school, to be used by a licensed registered professional nurse who is employed or contracted by the school district, or by a school employee who is trained to administer an epinephrine auto-injector. The policies must authorize a licensed registered professional nurse who is employed or contracted by the school district or a school employee who is trained in the administration of an epinephrine auto-injector to administer an epinephrine auto-injector to any student who has a prescription on file at the school. In addition, the policies must authorize administration of the drug to any other individual on the school grounds believed to be having an anaphylactic reaction. Finally, the policies must also require notification to the legal guardian of a student to whom an epinephrine auto-injector has been administered at school.

The bill specifies that a school employee who in good faith administered an epinephrine auto-injector to an individual consistent with the policies required in these bills would not

be liable in a criminal action or for civil damages as a result of an act or omission in the administration of the medication or epinephrine auto-injector, except for an act or omission amounting to gross negligence or willful and wanton misconduct.

House Bill 4353 (H-2) also requires that a multi-agency work group develop appropriate revisions to the "Medication Administration Guidelines" issued by the Michigan Department of Education. Under the bill, the department would work in conjunction with the Department of Community Health, and with input from the Michigan Association of School Nurses; the Michigan Nurses Association; the Michigan Parent Teacher Association; the American College of Allergy, Asthma, and Immunology; the Michigan Chapter of the American Academy of Pediatrics; the School-Community Health Alliance of Michigan; and other school health organizations and entities. Together, the members of the groups would be required to identify, develop, and adopt appropriate revisions to the "Medication Administration Guidelines," including but not limited to those relating to the specification of training needs and requirements for the administration and maintenance of stock epinephrine auto-injectors, including stocking of both junior and regular dose epinephrine auto-injectors, as necessary, and storage requirements.

Under the bill, at least annually, a school district would be required to report to the Michigan Department of Education (in the form and manner prescribed by the department), all instances of administration of an epinephrine auto-injector to a student at school. The reporting would have to include at least all of the following:

- the number of instances of administration of an epinephrine auto-injector to a student at school in a school year;
- the number of students who were administered an epinephrine auto-injector at school who were not previously known to be severely allergic; and
- the number of students who were administered an epinephrine auto-injector using the school's stock of epinephrine auto-injectors.

### ***BACKGROUND INFORMATION:***

For further information about severe allergic reactions, called anaphylaxis, as well as about prevention and treatment, visit the following websites:

- Allergy and Asthma Network, Mothers of Asthmatics at [www.aanma.org](http://www.aanma.org)
- American College of Allergy, Asthma & Immunology at [www.acaai.org](http://www.acaai.org)
- National Association of School Nurses at [www.nasn.org](http://www.nasn.org)

### ***ARGUMENTS:***

#### ***For:***

These bills are needed to ensure the health and safety of school children who suffer from severe allergic reactions (customarily to proteins found in the foods they eat, but also to insect venom). The bills will allow school officials to stock unassigned epinephrine auto-injectors and to administer the medication (without fear of liability) if students experience life-threatening anaphylaxis. The incidence of severe allergic reactions is on the rise.

Indeed, according to the CDC National Health Interview Survey (June 2009, updated 2011), throughout the United States, food allergies cause 30,000 cases of anaphylaxis and 150 deaths annually. If school personnel are trained to administer epinephrine auto-injectors, the adverse consequences from severe allergic reactions can be avoided. Michigan should join the 27 states that already require or allow school personnel to administer epinephrine when individuals in schools experience life-threatening allergic reactions.

***Response:***

The bills could be improved by offering greater consumer protection to the people who receive these medications and whose health and safety the bills are intended to protect. As the bills are now written, they will lower the standard of care for pharmacists to "gross negligence" rather than to the negligence standard that is already established in case law.

In particular, House Bill 4352 should be amended to clarify the liability protection afforded to pharmacists. Specifically, in House Bill 4352, the language offering liability protection in instances of injury or death caused by the "professional negligence or malpractice of the prescriber, dispensing prescriber, or pharmacist" should be removed. Instead, the bill should stipulate that a pharmacist who dispenses auto-injectable epinephrine is not liable in a civil action for a properly dispensed and stored device that was a proximate cause of injury or death to an individual due to the administration of or failure to administer the epinephrine auto-injector.

***POSITIONS:***

The Michigan Allergy and Asthma Society supports the bills. (9-18-13)

Michigan Anaphylaxis Advocacy Education supports the bills. (9-18-13)

The Michigan Council for Maternal and Child Health supports the bills. (9-18-13)

No Nuts Moms of Michigan support the bills. (9-18-13)

The Michigan Academy of Pediatrics supports the bills. (9-18-13)

The Michigan Pharmacists Association supports the bills. (9-18-13)

The Michigan Osteopathic Association supports the bills. (9-18-13)

Sanofi US/Auvi-Q supports the bills. (9-18-13)

Pfizer Pharmaceuticals supports the bills. (9-18-13)

The Michigan State Medical Society supports the bills. (9-18-13)

The Michigan Nurses Association supports the bills. (10-2-13)

The Michigan Association of School Nurses supports the bills in principle. (9-18-13)

The Michigan Association of School Boards opposes the bills. (9-18-13)

The Michigan Association for Justice opposes the bills. (9-18-13)

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■ This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.